Amendments to the Claims

The listing of claims will replace all prior versions, and listings of claims in the application.

1. (Previously presented) A method of preparing a lyophilized composition comprising:

(a) mixing

(i) polyoxyethylene (POE) and polyoxypropylene (POP) blockcopolymer;

(ii) a polynucleotide;

(iii) a cationic surfactant selected from the group consisting of benzalkonium chloride (BAK), benethonium chloride, cetrimide, cetylpyridinium chloride, acetyl triethylammonium chloride, (±)-N-(Benzyl)-N,N dimethyl-2,3-bis(hexyloxy)-1-propanaminium bromide (Bn-DHxRIE), (±)-N-(2 Acetoxyethyl)-N,N-dimethyl-2,3-bis(hexyloxy)-1-propanaminium bromide (DHxRIE-OAc), (±)-N-(2-Benzoyloxyethyl)-N,N- dimethyl-2,3-bis(hexyloxy)-1 propanaminium bromide (DHxRIE-OBz) and (±)-N-(3-Acetoxypropyl)-N,N dimethyl-2,3-bis(octyloxy)-1- propanaminium chloride (Pr-DOctRIE-OAc); and

(iv) a compound selected from the group consisting of monosaccharides, disaccharides, oligosaccharides, sorbitol, hydrophilic polymers, proteins and any combination thereof;

at a temperature below the cloud point of said block copolymer to form a mixture; and

(b) cold filtering the mixture, wherein filtration occurs at a temperature below the cloud point of the block copolymer; and

(c) lyophilizing the mixture;

wherein the lyophilized mixture form a stable, mono-dispersed composition upon reconstitution with an aqueous solution.

2. (Original) The method of claim 1, wherein said block copolymer is of the general formula: HO(C2H4O)x(C3H6O)y(C2H4O)xH; wherein (y) represents a number such that the molecular weight of the hydrophobic POP portion (C3H6O) is up to approximately 20,000 daltons and wherein (x) represents a number such that the percentage of the hydrophilic POE portion (C2H4O) is between approximately 1% and 50% by weight.

3. (Original) The method of claim 1, wherein said block copolymer is of the general formula: HO (C3H6O)y(C2H4O)x(C3H6O)yH; wherein (y) represents a number such that the molecular weight of the hydrophobic POP portion (C3H6O) is up to approximately 20,000 daltons and wherein (x) represents a number such that the percentage of the hydrophilic POE portion (C2H4O) is between approximately 1% and 50% by weight.

4. (Canceled)

5. (Original) The method of claim 1, wherein said mixing step (a) is performed at a temperature of about -2°C to about 8°C.

6. (Previously presented) The method of claim 1, wherein said cold filtration step is performed at a temperature of about -2°C to about 8°C.

7. (Original) The method of claim 4, wherein said cold filtration step is performed using a filter with a pore size of about 0.01 microns to about 2 microns.

8. (Original) The method of claim 2, wherein said block copolymer is CRL-1005.

9.-10. (Canceled)

11. (Previously presented) The method of claim 1, wherein said compound is sucrose.

12. (Canceled)

13. (Previously presented) The method of claim 1, wherein said mixture comprises about 1% to about 20% (w/v) of said compound.

14. (Original) The method of claim 11, wherein the final concentration of sucrose is about 10% (w/v).

15. (Original) The method of claim 1, wherein said mixture additionally comprises a pH stabilizing physiologic buffer.

16. (Original) The method of claim 15, wherein said physiologic buffer is selected from the group consisting of: saline, PBS, HEPES, MOPS, BIS-TRIS, sodium phosphate, potassium phosphate, dibasic sodium phosphate (Na2HPO4), monobasic sodium phosphate (NaH2PO4), monobasic sodium potassium phosphate (NaKHPO4), magnesium phosphate (Mg3(PO4)2·4H2O), or D(+)-□-sodium glycerophosphate (HOCH2CH(OH)CH2OPO3Na2).

17. (Original) The method of claim 16, wherein said physiologic buffer is sodium phosphate.

18. (Original) The method of claim 15, wherein the concentration of said physiologic buffer in the mixture is from about 5 mM to about 25 mM.

19. (Original) The method of claim 17, wherein said sodium phosphate is at a concentration of about 5 mM to about 25 mM.

20. (Original) The method of claim 1, wherein the final concentration of said cationic surfactant present in said mixture is from about 0.01 mM to about 5 mM.

21. (Original) The method of claim 1, wherein the final concentration of said block copolymer present in said mixture is from about 1mg/mL to about 50mg/mL.

22. (Original) The method of claim 1, wherein the final concentration of said polynucleotide molecules present in said mixture is from about 1ng/mL to about 10mg/mL.

23.-28. (Canceled)

29. (Previously presented) The method of claim 1, wherein said cationic surfactant is benethonium chloride.

30. (Previously presented) The method of claim 1, wherein said cationic surfactant is cetrimide.

31. (Previously presented) The method of claim 1, wherein said cationic surfactant is cetylpyridinium chloride.

32. (Previously presented) The method of claim 1, wherein the cationic surfactant is acetyl triethylammonium chloride.

33. (Previously presented) The method of claim 1, wherein said cationic surfactant is (±)-N-(Benzyl)-N,N dimethyl-2,3-bis(hexyloxy)-1-propanaminium bromide (Bn-DHxRIE).

34. (Previously presented) The method of claim 1, wherein said cationic surfactant is (±)-N-(2 Acetoxyethyl)-N,N-dimethyl-2,3-bis(hexyloxy)-1-propanaminium bromide (DHxRIE-OAc).

35. (Previously presented) The method of claim 1, wherein said cationic surfactant is (±)-N-(2-Benzoyloxyethyl)-N,N- dimethyl-2,3-bis(hexyloxy)-1 propanaminium bromide (DHxRIE-OBz).

36. (Previously presented) The method of claim 1, wherein said cationic surfactant is (±)-N-(3-Acetoxypropyl)-N,N dimethyl-2,3-bis(octyloxy)-1-propanaminium bromide (Pr-DOctRIE-OAc).

37. (Previously presented) The method of claim 1, wherein said compound is one or more monosaccharides.

38.-39. (Canceled)

40. (Previously presented) The method of claim 1, wherein said compound is one or more disaccharides.

41.-42. (Canceled)

43. (Previously presented) The method of claim 1, wherein said compound is one or more oligosaccharides.

44.-45. (Canceled)